K052817

APR 17 2006

Summary of Safety and Effectiveness
for
Eureka Infusion Pump
Models Eureka-IP & Eureka-LF

I. SMDA Information

510 K Summary
Prepared 09/21/2005

1. Submitted by:

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2. General Information

Classification Name: Infusion Pump : 880.5725
Common Name: Ambulatory Infusion Pump
Proprietary Name: Eureka-IP Infusion Pump, Eureka-LF Infusion Pump

Device Classification
Class II per CFR 880.5725
General Hospital and Personal Use Panel (80)
ProCodes : FRN - Infusion Pump
FPA - Intravenous (IV) Administration Set

3. Predicate Devices to which substantial equivalence is claimed

Home Pump- Block Medical **K896546**
SideKick - I-Flow Corporation **K923875**
MAXX - Medication Delivery Devices **K931458**

4. Device Description

The Eureka Infusion Pump and predicate devices functions with the use of restriction tubing. Pressure is exerted on a IV solution containers. When the air is pumped in to the bladder, the bladder enlarges. The pressure against the IV solution container forces the IV solution to flow through the administration set.

The Eureka Infusion Pump is designed to house a pre-filled IV solution container. The housing consists of Polycarbonate material for srtength. The administration sets are a PVC tubing set and attached spike of ABS plastic.

Performance characteristics also include the ability of sensors to determine pressure being exerted on the bag and the logic control to regulate this pressure by powering on and off the air pump, and venting pressure through a relief valve.

Each Eureka Pump Model is supplied with the following optional component/accessories
Pump, Recharger/Power Supply, Battery Pack, Carry Pack, Manual

The Eureka-IP and Eureka-LF Infusion Pumps are reusable.

Administration Set Description
The Eureka Administration set is a disposable device and intended for single patient use,.
Each Eureka Administration set is individually packaged and sold in cases of 25 each.

Eureka Administration Sets are provided sterile and all fluid path components are identical or equivalent to existing predicate administration set components

Power Requirements
The Eureka Infusion Pump requires battery pack (7.2V NiMH) supplied with pump or power supply (12V 1.25A) supplied with pump in order to operate.

The unit may be operated with the power supply while charging the battery pack.

5. Intended Use

The Eureka is ambulatory and intended for use in the hospital, home environment or alternate care sites for administration via intravemous cathether or central IV line or via the subcutaneous route.

The intended use of this device is for general use and the administration of intravenous antibiotics and chemotherapy drugs in solutions containers of 50mL to 100 mL. These indications and uses are the same as those of predicate devices.

6. Biologic Specifications
Biologic testing is in conformance with ISO 10993 Part 1 for all fluid path components of the Eureka Administration Sets

7. Chemical and Drug Specifications
No Specific drugs referenced in labeling of the Eureka Pump or Eureka Administration Sets

The Eureka pumps are intended for general infusions in solution volume of 50 to 100 mL via intravenous catheter, central IV line or subcutaneous route. (This device is not intended for use with Taxol)

8. Comparison to Predicate Devices.
The common technical characteristics of the SideKick, HomePump, MAXX and Eureka Infusion Pump is that each works by utilizing flow restriction tubing and the intravenous solution is forced through such tubing by means of pressure. The main difference between these devices are that the predicate device - HomePump uses Elastomeric material to pressurize the IV infusion solution and the SideKick uses a coiled spring to exert pressure a IV solution bag.

The Eureka and Maxx exert this pressure by a bladder inflated with air.

The source of energy to power the pump in Eureka is a 7.2V Battery Pack or Power supply/recharger.

The Eureka Infusion pumps and administration sets are substantially equivalent to predicate devices.

8b1. Non Clinical Trials to measure infusion over time
Non-clinical tests results demonstrate that the Eureka Infusion Pump has equivalent flow rate profiles and residual volume amounts. Also equivalent is the accuracy for labeled flow rates.
Results show. Operating temperature is 65-90° F

+/- 12 % labeled flow rate accuracy
97-99% of volume infused
97% flow accuracy based on profile

8b2. Clinical Trials

Clinical trials are not required

9. Packaging
The Eureka Administration Set packaging is suitable for radiation or ETO sterilization

10. Sterilization Information
The Eureka Administration sets are sterilized using Gamma Radiation

11. Conclusion
The conclusion of the Eureka Infusion Pump is that it is **safe, effective and equivalent** in performance to the HomePump, MAXX and Sidekick Infusion Devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 17 2006

Mr. Glenn Herskowitz
President
Universal Medical Technologies
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Larkspur, California 94977-5155

Re: K052817
Trade/Device Name: Eureka Infusion Pump, Models Eureka-IP, Eureka-LF
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN, FPA
Dated: March 23, 2006
Received: March 28, 2006

Dear Mr. Herskowitz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052817

Device Name: Eureka-IP Infusion Pump & Eureka-LF Infusion Pump

Indications for Use:

Infusions

Of volumes between 50 mL to 100 mL

Via Intravenous catheter or central IV line or subcutaneous route

In Ambulatory , Home or Hospital Setting

For General Use

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anthony D. Watson

Anthony D. Watson, General Hospital
Division of General Restorative Devices

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